CryoLife Files Application With FDA For Humanitarian Device Exemption for BioGlue

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Business Editors/Health and Medical Writers

ATLANTA--(BW HealthWire)--June 10, 1999--CryoLife, Inc. (NYSE:CRY), the leader in the development and commercialization of living human tissue implantable devices and a manufacturer and distributor of stentless heart valves and surgical adhesives, today announced that it has applied for a Humanitarian Device Exemption (HDE) approval from the Food and Drug Administration (FDA). The HDE approval is being sought for the Company's use of its BioGlue(R) surgical adhesive in the treatment of aortic dissections, a life-threatening condition which affects several thousand U.S. citizens annually. To encourage the development of medical devices for use in the treatment of rare conditions that affect small populations, the FDA is authorized to grant requests to exempt such devices from full compliance with clinical study requirements for premarket approval. The Company expects to receive a response from the FDA within 75 days.

On March 29, 1999, the Company received notification from the FDA that its BioGlue surgical adhesive had qualified for Humanitarian Use Device (HUD) designation, which is the first step in applying for HDE approval. CryoLife's surgical adhesive qualifies for HDE status consideration because it is designed to treat aortic dissections, a severe tear in the inner lining of the aorta, a condition that affects fewer than 4,000 patients annually.

Steven G. Anderson, President and Chief Executive Officer of CryoLife, said, "We are optimistic that BioGlue surgical adhesive will be approved by the FDA for HDE status because of its potential to increase the life expectancies of patients with aortic dissections. FDA approval could have positive implications for the several thousand patients who have aortic dissections each year."

BioGlue is a protein-based surgical adhesive which the Company has been distributing outside the United States since March 1998. BioGlue surgical adhesive is "CE" (product certification) marked in Europe for vascular and pulmonary repair applications. The potential market for use of BioGlue for vascular and pulmonary repairs is large, with some 500,000 aggregate pulmonary and vascular surgical procedures done annually in Europe.

Founded in 1984, CryoLife, Inc. is the leader in the development and commercialization of implantable living human tissues for use in cardiovascular, vascular, and orthopaedic surgeries throughout the United States and Canada. The Company's BioGlue(R) surgical adhesive, CE marked in the European Union for use in vascular and pulmonary sealing and repair, is distributed throughout Europe. The Company also manufactures CryoLife-O'Brien(R) and CryoLife-Ross(TM) stentless porcine heart valves which are distributed within the European Community.

Statements made in this letter which look forward in time involve risks and uncertainties and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such risks and uncertainties include the possibility that the FDA will not respond to the Company's BioGlue surgical adhesive HDE application within the anticipated 75 days, the possibility that the FDA will not approve the BioGlue surgical adhesive HDE application in a timely manner, if at all, or if approved, that surgeons may choose not to utilize BioGlue surgical adhesive, the possibility that BioGlue surgical adhesive could have currently unforeseen side effects which could render it undesirable for use in aortic dissections, changes in economic cycles, competition from other companies, changes in laws and governmental regulations applicable to the Company and other risk factors detailed in the Company's Securities and Exchange Commission filings, including the Company's Prospectus dated March 30, 1998 contained in its Registration Statement on Form S-3 (No. 333-46545).

Editor's Note: CryoLife Customer Service may be accessed by telephone: 1-800-438-8285 (U.S. and Canada) 1-770-419-3355 (International) 1-770-590-3753 (International fax) E-mail:customerservice@cryolife.com

Explanation of Terms:

Humanitarian Device Exemptions (HDE) are extended for devices that are used to treat or diagnose illnesses that affect fewer than 4,000 individuals in the United States; that would not be available to a person with the illness if the exemption were not granted; if no other comparable device is available to treat the illness; and if the device will not expose patients to an unreasonable or significant risk of illness or injury.

For additional information about the Company, visit CryoLife's web site: http://www.cryolife.com

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